Billing and Coding Guidelines:

Contractor Name
Wisconsin Physicians Service Insurance Corporation

Title
GSURG-052 Application of Bioengineered Skin Substitutes

CMS National Coverage
Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

CMS Publication 100-02, *Medicare Benefits Policy Manual Chapter 15*, section 100- Surgical Dressings.

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17, section 40 - Discarded Drugs and Biologicals

Coding Guidelines
Application of Bioengineered Skin Substitutes and Skin Grafting is performed on ulcers that are free of infection and underlying osteomyelitis.

Application of Skin substitute is a physician service (surgical procedure) and may only be covered when applied by a physician or Medicare non-physician practitioner such as a Physician Assistant, Clinical Nurse Specialists (CNS) or Nurse Practitioner (NP) in place of service inpatient hospital, outpatient hospital, ambulatory surgical center, or office setting:

Skin Replacement (CPT codes 15002 - 15005)
1. Per the definitions and the guidelines in *CPT Code Book* codes CPT codes 15002/15005 are not appropriate codes to use when performing a non-surgical application of a skin substitute.

Coding Guidelines
1. Significant debridement of a wound, performed before the application of a topical or local anesthesia is billed with CPT codes 11042 – 11047.
2. CPT codes 11043, 11046, 11044, and 11047 are usually appropriately billed in place of service inpatient hospital, outpatient hospital or ambulatory care center (ASC). Billing of these codes in another place of service is most likely a billing error and thus the service will be denied. If a provider feels that CPT 11043, 11046, 11044, or 11047 were actually performed in another place of service, a review of the denied claim should be requested and documentation, including an operative report, should be submitted.
3. Use CPT codes 15271 - 15278 for the surgical preparation or creation of recipient site for the tissue skin graft.
4. To bill for HCPCS Q4101, Apligraf per square centimeter, package (equal to 44-sq. cm.). If more than 44-sq. cm. is needed for additional grafting, bill according to the number of single units of HCPCS Q4101.
5. Payment for HCPCS Q4101 for any single ulcer will not be made for re-treatment within 1 year after initial treatment.
6. Medicare provides payment for the amount of the bioengineered skin substitute product that is reasonable and necessary to treat the patient's wound and will cover the amount of product discarded when billed according to national policy. Documentation requirements for unused/discarded materials are provided in coverage interpretive manuals: Internet Only Manual

(IOM): CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 17: 40 - Discarded Drugs and Biologicals.

7. When submitting a claim for skin substitutes, providers are required to accept assignment for this service. Providers, who do not accept assignment, should bill the skin product on a separate claim from other services performed on the same day.

OPPS/ASC Billing:

Skin Substitute Procedure Edits

Effective January 1, 2014, the payment for skin substitute products that do not qualify for pass-through status will be packaged into the payment for the associated skin substitute application procedure. The skin substitute products are divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products for packaging purposes.

Please see Change request 8572, 8575, and 8653 for additional instructions for OPPS billing.

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

Correct Reporting of Biologicals When Used As Implantable Devices
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In circumstances where the implanted biological has pass-through status as a device, separate payment for the device is made. In circumstances where the implanted biological does not have pass-through status, the OPPS payment for the implanted biological is packaged into the payment for the associated procedure.

When billing for biologicals where the HCPCS code describes a product that may either be surgically implanted or inserted or otherwise applied in the care of a patient, hospitals should not separately report the biological HCPCS codes, with the exception of biologicals with pass-through status, when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. Under the OPPS, hospitals are provided a packaged APC payment for surgical procedures that includes the cost of supportive items, including implantable devices without pass-through status. When using biologicals during surgical procedures as implantable devices, hospitals may include the charges for these items in their charge for the procedure, report the charge on an uncoded revenue center line, or report the charge under a device HCPCS code (if one exists) so these costs would appropriately contribute to the future median setting for the associated surgical procedure.

Hospitals are reminded that HCPCS codes describing skin substitutes (Q4100 – Q4130) should only be reported when used with one of the CPT codes describing application of a skin substitute (15271-15278). These Q codes for skin substitutes should not be billed when used with any other procedure besides the skin substitute application procedures.

Revision History/Explanation:
06/01/2015 Annual review, removed outdated information. No change to coverage.
08/01/2014 No change in coverage removed duplicate statements that are in the LCD. Removed statements that do not apply to this LCD, Added 2014 OPPS information.